

ACCOG CME WORKSHOP

Hormone Therapy Cases

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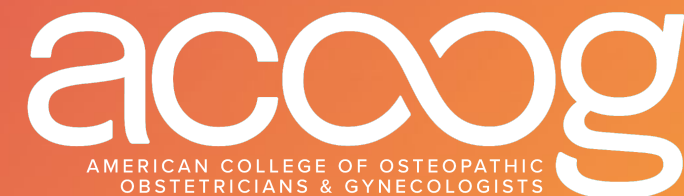
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01

Case A: Breast Cancer Survivor

Severe Night Sweats + Moderate Depression

Clinical Reasoning: NK3R Antagonist vs. SNRI vs. SSRI

DECISION POINT 1

Which VMS Agent for a Breast Cancer Survivor on Tamoxifen?

Hormone receptor-positive breast cancer survivor on tamoxifen. Severe night sweats, moderate depression. Which agent do you start for the vasomotor symptoms?

A Velafaxine - Start 37.5 mg/day (XR), titrate to a target of 75 mg/day for VMS]

B Elinzanetant 120 mg at bedtime

C Paroxetine 7.5 mg at bedtime

D Low-dose transdermal estradiol

DECISION POINT 1 - ANSWER

Which VMS Agent for a Breast Cancer Survivor on Tamoxifen?

Hormone receptor-positive breast cancer survivor on tamoxifen. Severe night sweats, moderate depression. Which agent do you start for the vasomotor symptoms?

A Velafaxine - Start 37.5 mg/day (XR), titrate to a target of 75 mg/day for VMS]

Venlafaxine is serotonergic at low doses and adds noradrenergic activity at higher doses.

B Elinzanetant 120 mg at bedtime

Dual NK1/NK3 antagonist studied in hormone receptor-positive breast cancer patients on endocrine therapy.

C Paroxetine 7.5 mg at bedtime

The only FDA-approved SSRI for VMS.

D Low-dose transdermal estradiol

Transdermal route lowers systemic exposure enough for survivors with stable disease.

Sources: Cardoso F, et al. Elinzanetant for vasomotor symptoms from endocrine therapy for breast cancer (OASIS 4). N Engl J Med. 2025. doi:10.1056/NEJMoa2415566. Randomized 474 women on tamoxifen or aromatase inhibitors to elinzanetant 120 mg or placebo; published June 2, 2025.
Pinkerton JV, Simon JA, Joffe H, et al. Elinzanetant for the treatment of vasomotor symptoms associated with menopause: OASIS 1 and 2 randomized clinical trials. JAMA. 2024;332(16):1343-1354. PMID 39172446.
National Comprehensive Cancer Network. NCCN Guidelines for Survivorship, Version 2.2025 (Hormone-Related Symptoms). Insights summary: J Natl Compr Canc Netw. 2025;23(6). PMID 40499584. The guideline was updated after OASIS-4 to list elinzanetant as a preferred nonhormonal option. Use the current NCCN.org version for the slide 9 screenshot.
Freeman EW, Guthrie KA, Caan B, et al. Efficacy of escitalopram for hot flashes in healthy menopausal women: a randomized controlled trial. JAMA. 2011;305(3):267-274. PMID 21245182.

Elinzanetant vs. Fezolinetant in Cancer Survivors

A key distinguishing factor for hormone-sensitive breast cancer patients



NCCN PREFERRED

Elinzanetant

- ✓ Dual NK1/NK3 antagonist · 120 mg daily
- ✓ OASIS-4 trial conducted specifically in HR-positive breast cancer patients on endocrine therapy
- ✓ Demonstrated improvements in VMS, sleep, and quality of life
- ✓ Bedtime dosing and CNS-depressant properties may aid sleep disruption



BOXED WARNING

Fezolinetant

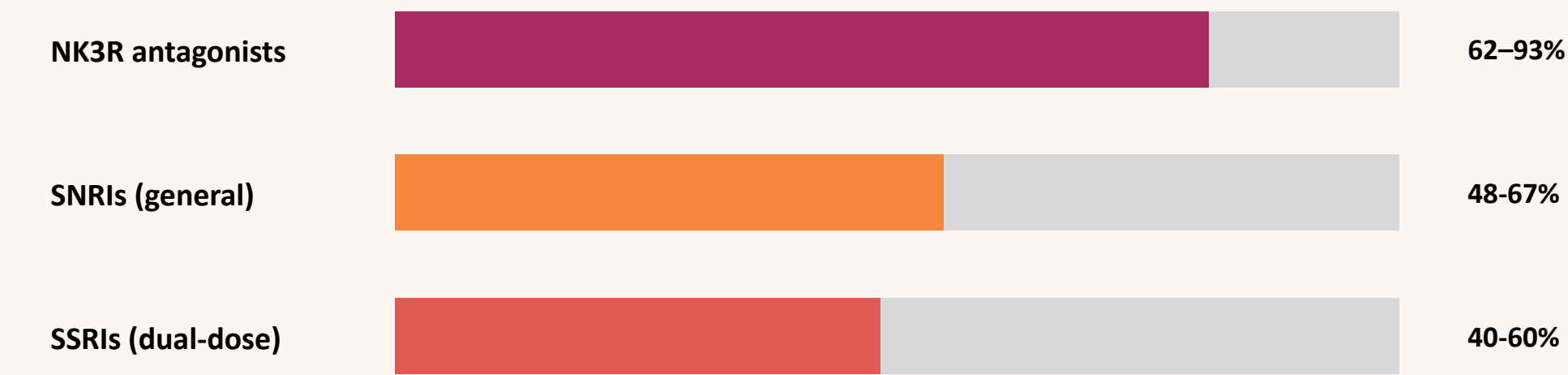
- ✓ Selective NK3 antagonist
- ✓ Excluded breast cancer patients from its pivotal trials
- ✓ Carries a more intensive liver monitoring schedule
- ✓ Less clinical certainty in this specific patient population

Sources: Cardoso F, et al. Elinzanetant for vasomotor symptoms from endocrine therapy for breast cancer (OASIS 4). N Engl J Med. 2025. doi:10.1056/NEJMoa2415566. Randomized 474 women on tamoxifen or aromatase inhibitors to elinzanetant 120 mg or placebo; published June 2, 2025.

Pinkerton JV, Simon JA, Joffe H, et al. Elinzanetant for the treatment of vasomotor symptoms associated with menopause: OASIS 1 and 2 randomized clinical trials. JAMA. 2024;332(16):1343-1354. PMID 39172446.

VMS Reduction by Agent Class

Percent reduction in vasomotor symptoms from baseline (range reported)



VMS Reduction (%)

Reported comparison across agent classes

AGENT CLASS	VMS REDUCTION	EXAMPLE/NOTE
NK3R antagonists	77.5	elinzanetant, fezolinetant
SNRI	60	venlafaxine
SSRI	50	escitalopram

The Clinical Question

Comorbid moderate depression + severe VMS in a hormone-sensitive cancer survivor.

Can a single agent treat both conditions?

The choice between an NK3R antagonist, a SNRI or SSRI



NK3R ANTAGONIST

Elinzanetant / Fezolinetant



SNRI

Venlafaxine



SSRI

Escitalopram

Which Antidepressant While She Stays on Tamoxifen?

Her PHQ-9 is 14 and she wants treatment for the depression, not just the night sweats. She will remain on tamoxifen. Which agent do you choose?

A Paroxetine 20 mg daily

B Fluoxetine 20 mg daily

C Venlafaxine - Start 37.5 mg/day (XR),
titrate to a target of 75 mg/day for VMS]

D Bupropion XL 150 mg daily

CASE A - DECISION POINT 2

Which Antidepressant While She Stays on Tamoxifen?

Her PHQ-9 is 14 and she wants treatment for the depression, not just the night sweats. She will remain on tamoxifen. Which agent do you choose?

A Paroxetine 20 mg daily

Strongest VMS evidence among SSRIs and treats depression at the same dose.

B Fluoxetine 20 mg daily

Long half-life, activating, inexpensive.

C **Venlafaxine - Start 37.5 mg/day (XR), titrate to a target of 75 mg/day for VMS**

Venlafaxine is serotonergic at low doses and adds noradrenergic activity at higher doses.

D Bupropion XL 150 mg daily

No sexual side effects, no weight gain.

Source: Breitbart, W. (2011). Do antidepressants reduce the effectiveness of tamoxifen?†. *Psycho-Oncology*, 20(1), 1–4. <https://doi.org/10.1002/pon.1872>

Managing Menopause After Cancer. *Lancet*. 2024. Hickey M, Basu P, Sassarini J, et al.

Nonhormonal Therapies for Menopausal Vasomotor Symptoms. *JN The Journal of the American Medical Association*. 2023. Christ JP, Navarro VM, Reed SD.

Liver Safety of the Dual Neurokinin-1/-3 Receptor Antagonist Elinzanetant Drug Safety. 2026. Lewis JH, Andrade RJ, Larrey D, et al.

Impact of elinzanetant on sleep disturbances and quality of life in women undergoing adjuvant endocrine therapy for breast cancer: Phase 3. OASIS 4 trial *Journal of Clinical Oncology*. 2025. Brennan D, Cardoso F, Briggs P, et al.

Recommended Prescription Plan

Dual-strategy approach given comorbid moderate depression

1

PRIMARY VMS AGENT

Elinzanetant 120 mg PO at bedtime (NCCN preferred in cancer survivors). Bedtime dosing and CNS-depressant properties may also help with night sweats and sleep disruption.

2

DEPRESSION

Venlafaxine 37.5 mg → 75 mg (NCCN-preferred SNRI) (also provides additive VMS benefit; mild CYP2D6 interaction, safe with tamoxifen)

3

TAMOXIFEN CAUTION

If the patient is on tamoxifen, avoid paroxetine and fluoxetine (strong CYP2D6 inhibitors).

4

ADJUNCTIVE – NIGHT SYMPTOMS

Consider adding gabapentin 300 mg at bedtime if night sweats remain disruptive despite the above (sedating properties help sleep).

Alternative Approach & Oncology Coordination

Balancing medication burden, symptom control, and oncology safety



ALTERNATIVE: SINGLE PATIENT APPROACH

If the patient prefers fewer medications:

Venlafaxine (an SNRI) is the single best first-line drug
– **Start 37.5 mg/day (XR), titrate to a target of 75 mg/day for VM**

Addresses both depression and VMS. VMS control
~60% reduction.



COORDINATION WITH ONCOLOGY

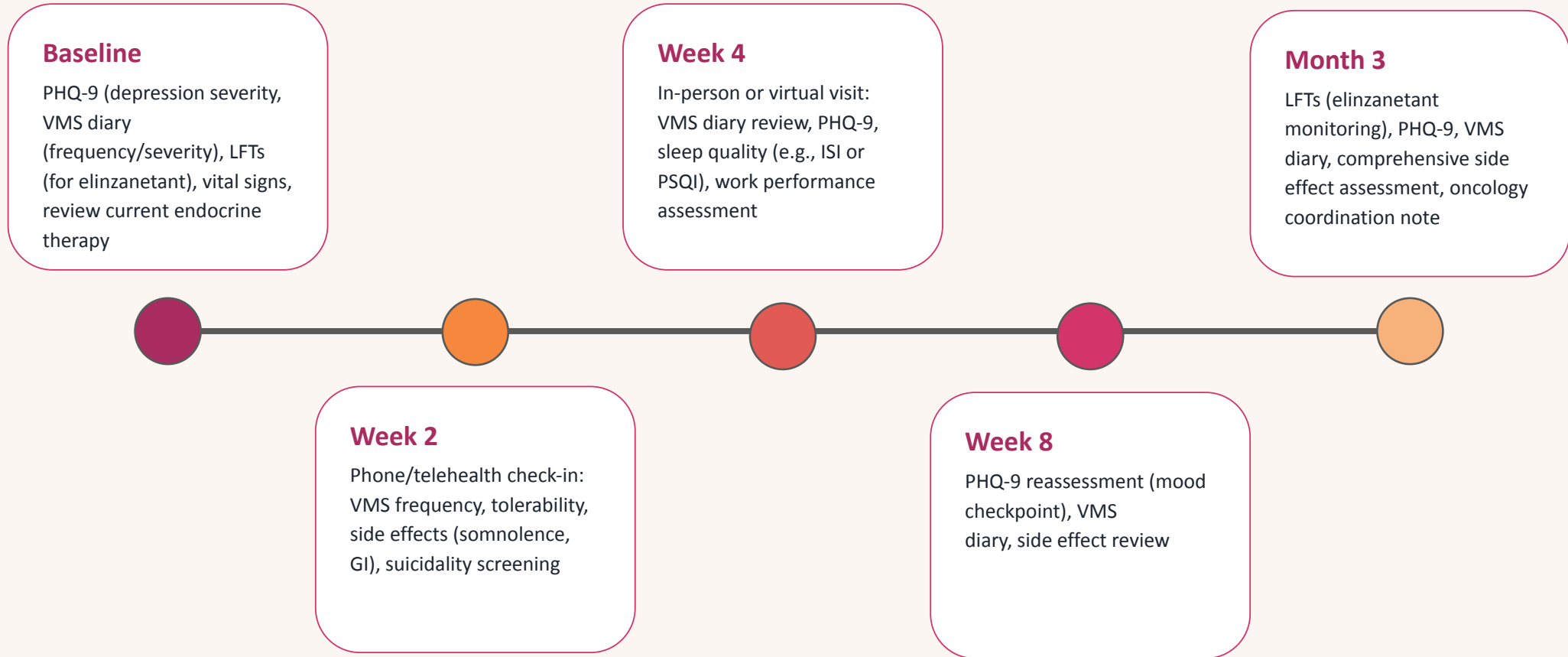
✓ Confirm current endocrine therapy (tamoxifen vs. aromatase inhibitor) to guide CYP2D6 interaction risk

✓ If elinzanetant is selected, check for interactions with CDK4/6 inhibitors

✓ Share the VMS management plan with the oncology team to ensure endocrine therapy adherence is not compromised



3 Month Monitoring Timeline



NCCN Survivorship Guidelines: Hormone-Related Symptoms

Nonhormonal VMS treatment for cancer survivors



National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2026

Survivorship: Hormone-Related Symptoms

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NON-HORMONAL PHARMACOLOGIC TREATMENTS AND DOSING FOR VASOMOTOR SYMPTOMS^a

Class	Drug	Commonly Used Daily Dose for Management of Vasomotor Symptoms	Comments (For maximum benefit, may increase to higher doses after a week as tolerated)
Antidepressants ^{b,c}	Venlafaxine ^d (SNRI) (preferred)	75 mg	• Start at lowest dose possible (25 mg or 37.5 mg) and increase as tolerated • Safe with tamoxifen ^{1,2} • CYP2D6 mild interaction
	Desvenlafaxine (SNRI)	100 mg	• Start at lowest dose possible (25 mg or 50 mg) and increase as tolerated • CYP2D6 mild interaction
	Escitalopram (SSRI)	20 mg	• Start at lowest dose possible (10 mg) and increase as tolerated • CYP2D6 mild interaction
	Citalopram (SSRI)	20 mg	• Start at lowest dose possible (10 mg) and increase as tolerated • CYP2D6 mild interaction
	Sertraline (SSRI) ^e	50 mg	• Start at lowest dose possible (25 mg) and increase as tolerated • Limited data on effectiveness • Use with caution for survivors on tamoxifen • CYP2D6 moderate interaction • CYP3A4 moderate interaction
	Paroxetine (SSRI) ^f	Low-dose 7.5 mg or Standard paroxetine short acting up to 20 mg, controlled release up to 25 mg	• Low-dose (7.5 mg) paroxetine is an FDA-approved alternative to hormones for hot flashes • Use with caution for survivors on tamoxifen • CYP2D6 strong interaction
	Fluoxetine (SSRI) ^g	20 mg	• Start at lowest dose possible (10 mg) and increase as tolerated • Limited data on effectiveness • Use with caution for survivors on tamoxifen • CYP2D6 strong interaction • CYP3A4 moderate interaction

[Footnotes on SHRS-A 3 of 3](#)
[References on SHRS-A 3 of 3](#)

Note: All recommendations are category 2A unless otherwise indicated.

SHRS-A
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Survivorship: Hormone-Related Symptoms

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NON-HORMONAL PHARMACOLOGIC TREATMENTS AND DOSING FOR VASOMOTOR SYMPTOMS^a

Class	Drug	Commonly Used Daily Dose for Management of Vasomotor Symptoms	Comments (For maximum benefit, may increase to higher doses after a week as tolerated)
Anti-convulsants	Gabapentin ^d (preferred)	900 mg (typically 300 mg 3 times a day)	• Start at lowest dose possible (100 mg or 300 mg) and increase as tolerated • Consider starting at night time as this drug tends to cause sedation
	Pregabalin	150–300 mg	Start at lowest dose possible (25 mg) and increase as tolerated
Antimuscarinic anticholinergic	Oxybutynin ³	5–10 mg	Start with 2.5–5 mg BID, typically used for overactive bladder and may cause urinary retention along with other anticholinergic side effects
Selective neurokinin-1 (NK1) and/or neurokinin-3 (NK3) receptor antagonists	Elinzanetant (preferred)	120 mg PO once daily at bedtime with or without food	• An FDA-approved alternative to hormones for the treatment of moderate to severe vasomotor symptoms due to menopause. • Side effects: ▶ Risk for liver injury. Perform liver function tests (LFTs) prior to initiation. LFTs should be checked at baseline and at month 3 or if symptoms suggest liver injury. ▶ CNS depressant effect and daytime impairment: Patients should be advised about the potential for somnolence and other nervous system effects. Those who experience these effects should refrain from driving or engaging in hazardous occupations or activities. • The original trial was performed in individuals receiving endocrine therapy for hormone receptor (HR)-positive breast cancer.
	Fezolinetant	45 mg PO once daily with or without food	• An FDA-approved alternative to hormones for the treatment of moderate to severe vasomotor symptoms due to menopause. • Side effects: Risk for liver injury. Perform LFTs prior to initiation. LFTs should be checked at baseline, at months 1, 2, 3, 6, and 9 or if symptoms suggest liver injury. • In the original trials, patients with breast cancer were excluded.

[Footnotes on SHRS-A 3 of 3](#)
[References on SHRS-A 3 of 3](#)

Note: All recommendations are category 2A unless otherwise indicated.

SHRS-A
2 OF 3

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02

Case B: VMS with Cardiovascular, Metabolic & Psychological Comorbidity

Healthy-Appearing 51-Year-Old — High FRAX, Moderate VMS, and Anxiety

The Patient



CLINICAL PICTURE

- ✓ 51 years old, appears healthy, no stated contraindications to HT
- ✓ High FRAX score — elevated fracture risk despite outward health
- ✓ Moderate VMS — hot flashes present but not severe
- ✓ Untreated anxiety with disrupted sleep — never formally addressed



CLINICAL PICTURE

- ✓ No contraindication — she is a genuine hormone therapy candidate
- ✓ One well-chosen HT regimen can serve three goals: VMS, bone protection, and sleep
- ✓ Anxiety is a separate problem
- ✓ The real decision: treat HT first, or refer for anxiety immediately?

Treat the VMS First, or Refer for Anxiety First?

51-year-old, healthy, no contraindications to hormone therapy. Moderate VMS, high FRAX score, untreated anxiety with disrupted sleep. What is your first move?

A Refer for anxiety treatment and defer hormone therapy

B Start an SSRI to cover anxiety and VMS in one prescription

C Start transdermal estradiol plus micronized progesterone, set a Week 6 anxiety checkpoint

D Start alendronate for bone and gabapentin for night symptoms

Treat the VMS First, or Refer for Anxiety First?

51-year-old, healthy, no contraindications to hormone therapy. Moderate VMS, high FRAX score, untreated anxiety with disrupted sleep. What is your first move?

A Refer for anxiety treatment and defer hormone therapy

Mental health comes first; VMS can wait.

B Start an SSRI to cover anxiety and VMS in one prescription

Single agent, two problems.

C Start transdermal estradiol plus micronized progesterone, set a Week 6 anxiety checkpoint

One regimen for VMS, bone protection, and sleep, with a defined reassessment.

D Start alendronate for bone and gabapentin for night symptoms

Addresses fracture risk and sleep without hormones.

Sources: The 2022 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2022;29(7):767-794. PMID 35797481. For women younger than 60 or within 10 years of menopause onset with no contraindications, the benefit-risk ratio is favorable for treatment of VMS and prevention of bone loss.
Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. *Menopause*. 2021;28(9):973-997.
ACOG Practice Bulletin No. 141: Management of menopausal symptoms. *Obstet Gynecol*. 2014;123(1):202-216. Reaffirmed 2024. Efficacy of Hormone Therapy and Phytoestrogens on the Psychological Symptoms of Menopausal Women: A Systematic Review, Meta-Analysis, and Trial Sequential Analysis *Frontiers in Medicine*. 2026. Shou M, Ye M, Lou C, et al.
Antidepressant Medications and Osteoporosis Bone. 2012. Rizzoli R, Cooper C, Reginster JY, et al.
Depression, Antidepressants, and Bone Health in Older Adults: A Systematic Review *Journal of the American Geriatrics Society*. 2014. Gebara MA, Shea ML, Lipsey KL, et al.
Use of serotonin reuptake inhibitors and risk of subsequent bone loss in a nationwide population-based cohort study. *Scientific Reports*. 2021. Kang S, Han M, Park CI, et al.
Selective serotonin reuptake inhibitor and selective serotonin and norepinephrine reuptake inhibitor use and risk of fractures in adults: A systematic review and meta-analysis *International Journal of Geriatric Psychiatry*. 2018. Khanassov V, Hu J, Reeves D, van Marwijk H.

CLINICAL REASONING

One Regimen, Three Problems

Systemic estrogen is FDA-approved for osteoporosis prevention in appropriate candidates — a high-FRAX, VMS-positive 51-year-old is exactly that candidate.



VMS RELIEF



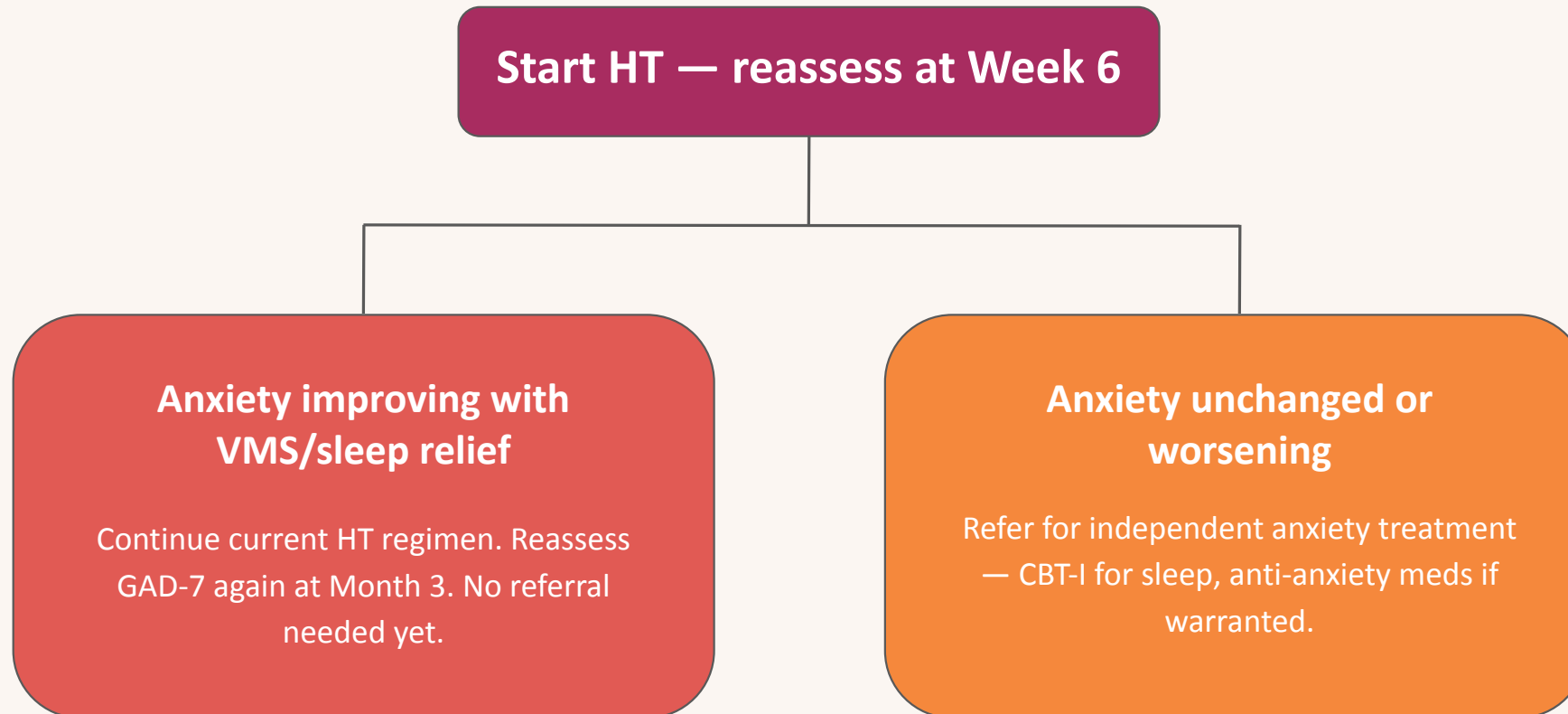
BONE PROTECTION



SLEEP IMPROVEMENT

Sources: The 2022 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2022;29(7):767-794. PMID 35797481. For women younger than 60 or within 10 years of menopause onset with no contraindications, the benefit-risk ratio is favorable for treatment of VMS and prevention of bone loss.
Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. *Menopause*. 2021;28(9):973-997.

WHEN TO ADD OR REFER FOR MENTAL HEALTH CARE



TAKEAWAY

Prescription Plan

1

Transdermal Estradiol Patch

0.05 mg/day, applied twice weekly

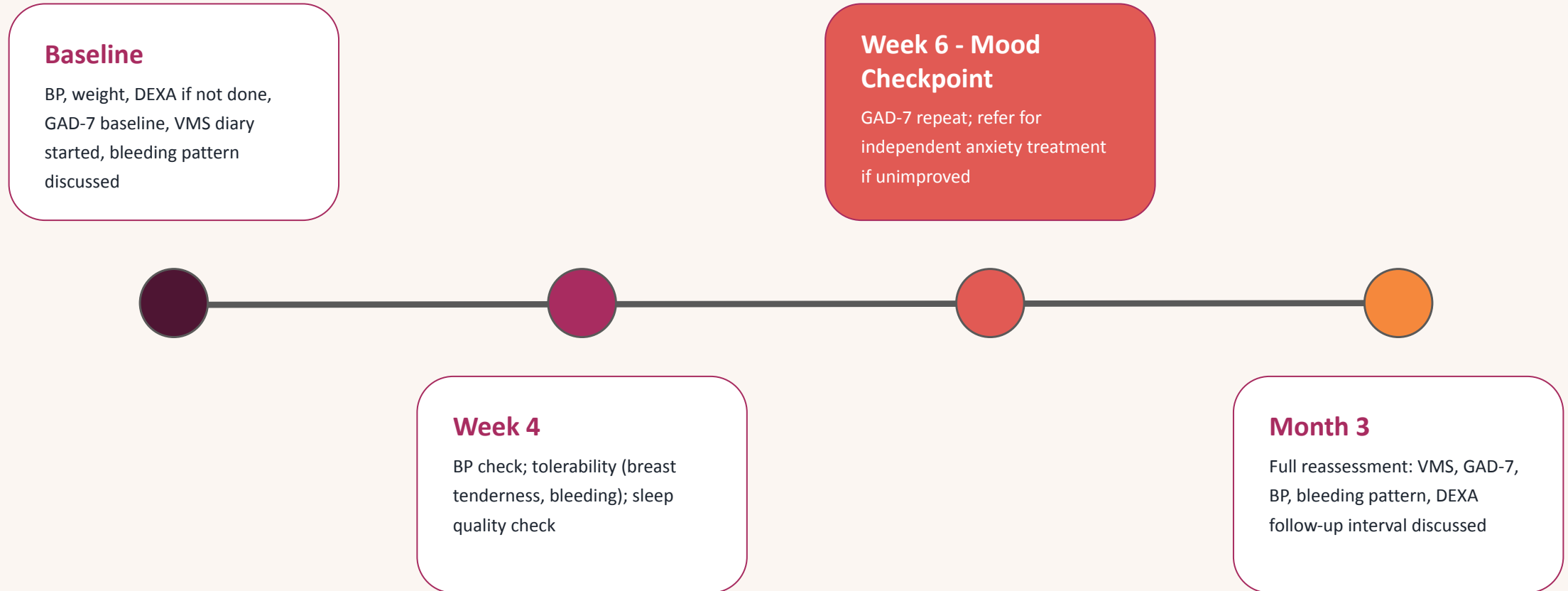
2

Micronized Progesterone

100–200 mg PO nightly (cyclic or continuous)

Sources: The 2022 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2022;29(7):767-794. PMID 35797481. For women younger than 60 or within 10 years of menopause onset with no contraindications, the benefit-risk ratio is favorable for treatment of VMS and prevention of bone loss.
Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. *Menopause*. 2021;28(9):973-997.
ACOG Practice Bulletin No. 141: Management of menopausal symptoms. *Obstet Gynecol*. 2014;123(1):202-216. Reaffirmed 2024.

3 Month Monitoring Timeline



Source: Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092-1097.

Case B Takeaway

Dual-strategy approach given comorbid moderate depression

- 1** A high FRAX score reframes hormone therapy as a bone-protective necessity
- 2** One transdermal estradiol + micronized progesterone regimen serves VMS, bone, and sleep simultaneously
- 3** Progesterone's GABA-A-mediated sedative effect is a genuine, useful side benefit for the sleep complaint
- 4** The Week 6 checkpoint is the safeguard — anxiety that doesn't move with VMS/sleep relief needs its own referral

03

Case C: Severe VMS in a Patient Who Cannot Take Estrogen

*54-Year-Old With Prior Unprovoked Pulmonary Embolism, No
Mood Disorder, Night-Shift Work*

The Patient



CLINICAL PICTURE

- 54 years old, final menstrual period 3 years ago
- Severe VMS: 10 to 12 hot flashes daily, night sweats waking her 3 to 4 times nightly
- Unprovoked pulmonary embolism at 49; completed 6 months of anticoagulation. Hematology advised against exogenous estrogen
- BMI 31, blood pressure 128/80, nonsmoker, no alcohol
- PHQ-9 = 2, GAD-7 = 3. No depression or anxiety
- Registered nurse on rotating 12-hour night shifts
- Labs: ALT 22, AST 20, bilirubin normal, eGFR 88
- Medications: none. Supplements: none



WHY THIS CASE IS DIFFERENT

- Hormone therapy is off the table. Prior unprovoked venous thromboembolism (VTE) is a contraindication, by any route
- No mood disorder, so an SSRI or SNRI brings no dual benefit here
- She names two priorities: stay alert on shift and avoid sexual side effects
- No liver disease, normal renal function, no interacting drugs
- The real decision: which nonhormonal agent has the strongest evidence and the fewest trade-offs for this patient?

DECISION POINT 1

Which Agent Do You Start?

Severe VMS, prior unprovoked PE, no depression or anxiety, night-shift nurse, normal liver and kidney function. What is the best first-line choice?

A Transdermal estradiol 0.025 mg plus micronized progesterone

B Venlafaxine XR 75 mg daily

C Fezolinetant 45 mg daily

D Gabapentin 900 mg at bedtime

DECISION POINT 1 - ANSWER

Which Agent Do You Start?

Severe VMS, prior unprovoked PE, no depression or anxiety, night-shift nurse, normal liver and kidney function. What is the best first-line choice?

A **Transdermal estradiol 0.025 mg plus micronized progesterone**

Transdermal route carries lower VTE risk than oral, so the contraindication does not apply.

B **Venlafaxine XR 75 mg daily**

Level I nonhormonal option with the longest track record in VMS.

C **Fezolinetant 45 mg daily**

Selective NK3 receptor antagonist. Level I evidence in women unsuitable for hormone therapy.

D **Gabapentin 900 mg at bedtime**

Sedating, so it also covers the night sweats and sleep disruption.

Sources: The 2023 nonhormone therapy position statement of The North American Menopause Society. Menopause. 2023;30(6):573-590. PMID 37252752. Fezolinetant recommended at Level I alongside SSRIs/SNRIs and gabapentin. Schaudig K, Wang X, Bouchard C, et al. Efficacy and safety of fezolinetant for moderate-severe vasomotor symptoms associated with menopause in individuals unsuitable for hormone therapy: phase 3b randomised controlled trial (DAYLIGHT). BMJ. 2024;387:e079525. Unsuitability was defined as contraindicated, caution, stoppers, or averse, which covers the VTE history in this case. Lederman S, Ottery FD, Cano A, et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1). Lancet. 2023;401(10382):1091-1102. PMID 36924778. Johnson KA, Martin N, Nappi RE, et al. Efficacy and safety of fezolinetant in moderate to severe vasomotor symptoms associated with menopause: a phase 3 RCT (SKYLIGHT 2). J Clin Endocrinol Metab. 2023;108(8):1981-1997. doi:10.1210/clinem/dgad058. Neal-Perry G, Cano A, Lederman S, et al. Safety of fezolinetant for vasomotor symptoms associated with menopause: a randomized controlled trial (SKYLIGHT 4). Obstet Gynecol. 2023;141(4):737-747. PMID 36897180. Efficacy and Safety of Fezolinetant for Moderate-Severe Vasomotor Symptoms Associated With Menopause in Individuals Unsuitable for Hormone Therapy: Phase 3b Randomised Controlled Trial m BMJ. 2024. Schaudig K, Wang X, Bouchard C, et al. Fezolinetant (Veozah) for the Treatment of Menopause Symptoms American Family Physician. 2024. Cortney Crespo, MD, Deborah Erlich, MD, MMedEd VEOZAH DA Food and Drug Administration. Updated date: 2026-02-26.

Why Fezolinetant Is the Guideline Choice Here

1

Guideline Position

- The Menopause Society 2023 Nonhormone Therapy Position Statement: fezolinetant recommended, Level I evidence
- Same evidence tier as SSRIs/SNRIs and gabapentin, with larger effect size
- Explicitly intended for women who cannot or choose not to use hormone therapy

2

Evidence in This Population

- SKYLIGHT 1 and 2: roughly 60% reduction in VMS frequency at 12 weeks, onset within 1 week
- DAYLIGHT (2024): same magnitude of benefit in women considered unsuitable for hormone therapy, including VTE history
- Sustained through 52 weeks in SKYLIGHT 4

3

Fit With Her Priorities

- No sedation or dizziness: safe for a night-shift nurse
- No sexual dysfunction or weight gain, unlike SSRIs/SNRIs
- No anticholinergic burden, unlike oxybutynin
- Once daily, no titration, no taper

Sources: The 2023 nonhormone therapy position statement of The North American Menopause Society. *Menopause*. 2023;30(6):573-590. PMID 37252752. Fezolinetant recommended at Level I alongside SSRIs/SNRIs and gabapentin. Schaudig K, Wang X, Bouchard C, et al. Efficacy and safety of fezolinetant for moderate-severe vasomotor symptoms associated with menopause in individuals unsuitable for hormone therapy: phase 3b randomised controlled trial (DAYLIGHT). *BMJ*. 2024;387:e079525. Unsuitability was defined as contraindicated, caution, stoppers, or averse, which covers the VTE history in this case. Lederman S, Ottery FD, Cano A, et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1). *Lancet*. 2023;401(10382):1091-1102. PMID 36924778. Johnson KA, Martin N, Nappi RE, et al. Efficacy and safety of fezolinetant in moderate to severe vasomotor symptoms associated with menopause: a phase 3 RCT (SKYLIGHT 2). *J Clin Endocrinol Metab*. 2023;108(8):1981-1997. doi:10.1210/clinem/dgad058. Neal-Perry G, Cano A, Lederman S, et al. Safety of fezolinetant for vasomotor symptoms associated with menopause: a randomized controlled trial (SKYLIGHT 4). *Obstet Gynecol*. 2023;141(4):737-747. PMID 36897180.

DECISION POINT 2

What Must Happen Before the First Dose?

You have chosen fezolinetant 45 mg daily. Which step is required before you send the prescription?

A None. Start today and check labs at the 3-month visit

B Baseline hepatic panel and full medication review for CYP1A2 inhibitors

C Screening mammogram and pelvic ultrasound

D Baseline electrocardiogram

Audience: select one answer (A, B, C, or D) before the reveal.

What Must Happen Before the First Dose?

You have chosen fezolinetant 45 mg daily. Which step is required before you send the prescription?

A None. Start today and check labs at the 3-month visit

Labs were normal at her annual exam 8 months ago.

B Baseline hepatic panel and full medication review for CYP1A2 inhibitors

ALT, AST, alkaline phosphatase, total and direct bilirubin. Confirm no cirrhosis, no severe renal impairment, no fluvoxamine, ciprofloxacin, mexiletine, or cimetidine.

C Screening mammogram and pelvic ultrasound

Standard pre-treatment imaging for any menopause therapy.

D Baseline electrocardiogram

NK3 receptor antagonists carry a QT prolongation warning.

Prescription Plan

1

Fezolinetant 45 mg PO once daily

- Onset: symptom reduction by week 1, near-maximal effect by week 4
- Most common adverse effects: abdominal pain, diarrhea, insomnia, back pain, hot flush (each under 5%)
- Counsel on liver warning symptoms.
- Prior authorization is routine.
- No dose adjustment for mild or moderate renal impairment. Avoid in moderate or severe hepatic impairment

Adjuncts and Alternatives

- Cognitive behavioral therapy for VMS and sleep
- If fezolinetant fails or is not covered: elinzanetant 120 mg at bedtime or venlafaxine XR 37.5 to 75 mg
- Skip gabapentin and oxybutynin for this patient

DECISION POINT 3

Week 6: An Antibiotic Enters the Picture

She is doing well: hot flashes down from 12 to 4 per day, sleeping through most nights. She calls because urgent care prescribed ciprofloxacin 250 mg twice daily for 3 days for cystitis. What do you advise?

A Take both. A 3 day course is too short to matter

B Replace ciprofloxacin with nitrofurantoin or fosfomycin and continue fezolinetant

C Stop fezolinetant permanently and switch to escitalopram

D Cut fezolinetant to every other day during the antibiotic course

Audience: select one answer (A, B, C, or D) before the reveal.

Week 6: An Antibiotic Enters the Picture

She is doing well: hot flashes down from 12 to 4 per day, sleeping through most nights. She calls because urgent care prescribed ciprofloxacin 250 mg twice daily for 3 days for cystitis. What do you advise?

A Take both. A 3 day course is too short to matter

Interaction warnings target long-term coadministration.

B Replace ciprofloxacin with nitrofurantoin or fosfomycin and continue fezolinetant

If a fluoroquinolone is truly required, hold fezolinetant for the course and resume after.

C Stop fezolinetant permanently and switch to escitalopram

Any interaction signals the drug is too fragile for real-world use.

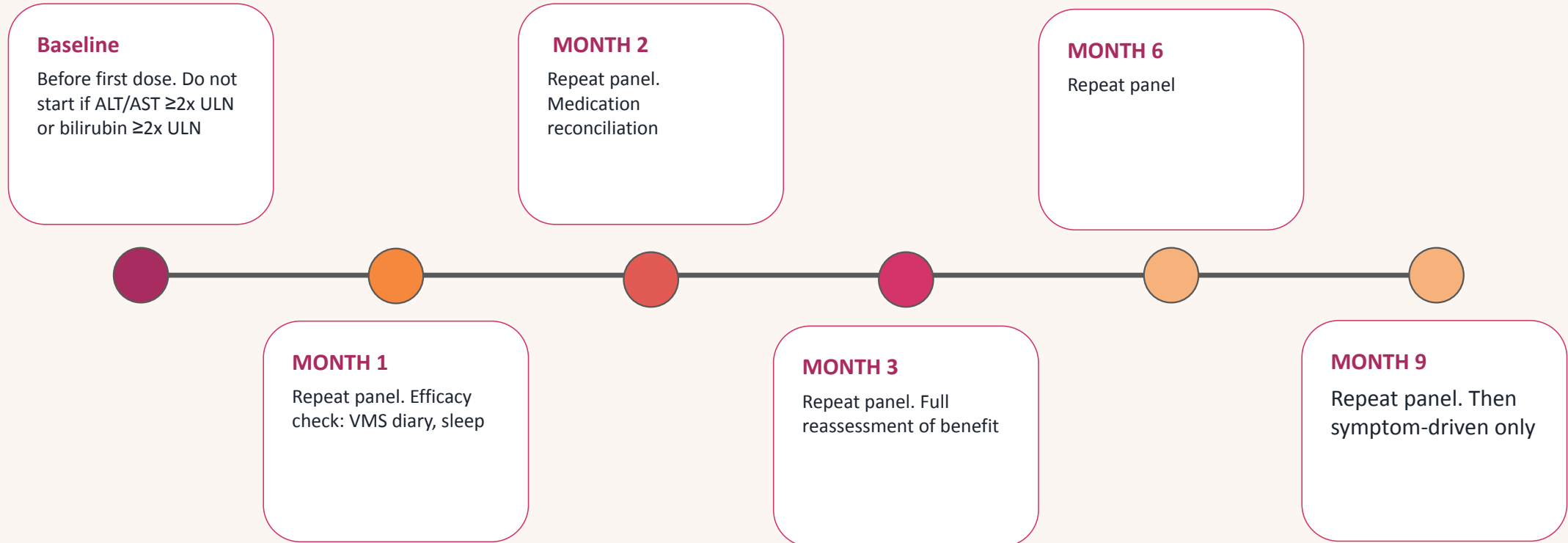
D Cut fezolinetant to every other day during the antibiotic course

Halves exposure and preserves symptom control.

MONITORING PLAN

Liver Monitoring Timeline (FDA Label, December 2024)

Six scheduled hepatic panels in the first 9 months. Each panel: ALT, AST, alkaline phosphatase, total and direct bilirubin.



Sources: VEOZAH (fezolinetant) US Prescribing Information. Astellas; revised December 2024. Contraindicated with known cirrhosis, severe renal impairment or end-stage renal disease, and concomitant CYP1A2 inhibitors. [astellas.com/content/dam/astellas-com/global/en/documents/veozah_uspi.pdf](https://www.astellas.com/content/dam/astellas-com/global/en/documents/veozah_uspi.pdf)
US Food and Drug Administration. Drug Safety Communication: FDA adds warning about rare occurrence of serious liver injury with use of Veozah (fezolinetant). December 16, 2024. Added monthly liver testing for the first 2 months after starting, then at months 3, 6, and 9.

KEY TAKEAWAYS

Case C: The Takeaway

- 1** Prior unprovoked VTE removes estrogen by any route.
- 2** Fezolinetant is the highest-efficacy nonhormonal option with Level I evidence, and DAYLIGHT proved it in exactly this population
- 3** When there is no mood disorder, SSRIs and SNRIs lose their dual-benefit argument and keep their sexual side effects
- 4** Baseline labs, six scheduled hepatic panels, and a CYP1A2 interaction check are part of the prescription
- 5** Common short courses (ciprofloxacin, fluvoxamine, cimetidine) are contraindicated.

Case A References

Case A: Breast cancer survivor on tamoxifen, severe VMS, moderate depression

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Case B References

Case B: Healthy 51-year-old, high FRAX, moderate VMS, untreated anxiety

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Case C References

Prior unprovoked PE, severe VMS

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QUESTIONS

Thank you.

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